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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,772	11/14/2003	Yoshihiro Mori	09496/0200199-US0	8762

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EXAMINER	
CRAIG, PAULA L	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,772	MORI ET AL.	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-6, drawn to a blood purification device having a water removing means, classified in class 604, subclass 5.01.

   II. Claim 7, drawn to a blood purification method including a step of changing a rate and a step of identifying a malfunction, classified in class 128, subclass 898.

2. The inventions are distinct, each from the other because:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed could be practiced with a product that did not include a water removing means, and the product as claimed could be used for blood purification without including a step of changing a rate or identifying a malfunction.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Louis DelJuidice on May 18, 2006, a provisional election was made without traverse to prosecute the invention of Group I, Claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claim 7 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

6. Claim 2 is objected to because of the following informalities: In Claim 2, the phrase "a blood purifier connected between said arterial blood circuit and said venous blood circuit" should be eliminated as redundant, since this element was introduced in Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-6 are rejected under 35 U.S.C. 102(a) as being anticipated by, or in the alternative under 35 U.S.C. 103(a) as obvious over, U.S. Patent No. 6,554,789 to Brugger et al.

For Claim 1, Brugger teaches a blood purification device having a blood circuit with an arterial blood circuit and a venous blood circuit (Fig. 11, col. 1, lines 15-17, and col. 9, line 24 to col. 10, line 24). A blood purifier is connected between the arterial blood circuit and the venous blood circuit, and purifies the blood flowing in the blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A first measuring means is disposed in the arterial blood circuit for measuring the blood concentration of the arterial blood circuit (upstream sensor measuring pre-treatment hematocrit, col. 24, lines 8-14). A second measuring means is disposed in the venous blood circuit for measuring a blood concentration of the venous blood circuit (downstream sensor for post-treatment hematocrit, col. 24, lines 14-21). Brugger teaches a calculating means for calculating a ratio of the blood concentrations measured by the first measuring means and the second measuring means (col. 24, lines 21-34). Brugger also teaches finding the blood concentration ratio as a theoretical value obtained by a designated formula using a

preset blood flow rate and the blood purifying rate of the blood purifier as parameters (col. 21, lines 24-53 and col. 24, lines 21-31). Brugger teaches an evaluation means (col. 24, lines 21-34). Having the evaluation means evaluate whether the blood concentration ratio obtained from the calculating means as a measurement value and the blood concentration ratio as a theoretical value are approximately equal is considered to be inherent in Brugger (adjusted to zero, col. 24, lines 12-34). The burden to show that this, in fact, is not the case is shifted to Applicant as per *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980).

11. For Claim 2, Brugger teaches a blood purifier connected between the arterial blood circuit and the venous blood circuit (hemofilter 34, Fig. 11 and col. 5, lines 58-64). A water removing means is connected to the blood purifier for removing water from the blood flowing in the blood purifier (ultrafiltration and removal of waste fluid, col. 6, lines 43-60, col. 7, lines 26-30, col. 20, lines 41-67, col. 21, line 24 to col. 22, line 3, and col. 23, line 43 to col. 24, line 34). The purifying rate is the same as the water removal rate of the water removing means (col. 21, line 24 to col. 24, line 34).

12. For Claim 3, Brugger teaches a substitution fluid supplying means disposed to supply substitution fluid into the blood circuit (replacement fluid, col. 1, lines 37-42, col. 6, lines 1-7, and col. 20, lines 47-54). Brugger teaches a calculating means for calculating the ratio of the blood concentrations calculated as a theoretical value by the designated formula using the substitution fluid supplying rate preset for the substitution fluid supplying means and a filtration rate for the blood purifier in addition to the preset

blood flow rate and the preset water removal rate as parameters (col. 6, lines 43-63, col. 20, line 41 to col. 22, line 59, and col. 23, line 43 to col. 24, line 34).

13. For Claims 4, 5, and 6, Brugger teaches a reporting means for reporting the ratio difference between the blood concentration as a measurement value and the blood concentration as the theoretical value being bigger than the designated acceptable number by the evaluation means (col. 21, line 24 to col. 22, line 59, and col. 24, lines 21-34).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-3 of copending Application

No. 11/209,278 to Tarumi et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because they include hematocrit sensors in both the arterial circuit and the venous circuit.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,923,598 to Schal shows sensors located both upstream and downstream of a blood purifier. U.S. Patent Nos. 6,200,485 to Kitaevich et al., 6,821,441 to Pedrini et al., and U.S. Patent Application Publication No. 2004/0068219 to Summerton teach hemofiltration systems in which patient parameters such as blood concentration are monitored and the system responds accordingly. U.S. Patent No. 6,582,656 to Steuer et al. teaches a photometric sensor measuring blood concentration. The remaining prior art references listed on the accompanying Form PTO-892 show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER